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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,862

09/30/2005

Roman Stauch

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BACHMAN & LAPOINTE, P.C.

900 CHAPEL STREET

SUITE 1201

NEW HAVEN, CT 06510

EXAMINER

SIGLER, JAY R

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/551,862	Applicant(s) STAUCH, ROMAN	
	Examiner JAY R. SIGLER	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 18-20 and 23-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 18-20 and 23-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 January 2009 has been entered.

Specification

2. Claims 20 and 27 is objected to because of the following informalities: in claim 20, line 3, the language "a drive unit" should be "the drive unit" for continuity with claim 15; in claim 27, line 3, "a motor element" should be "the motor element" for continuity. It is noted that the disclosed invention has one drive unit. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 15, 18-20, and 23-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

Art Unit: 3775

subject matter which applicant regards as the invention.

In claim 15: the language "comprising at least two elements" (l. 2) and "the guide element is secured in the holes of the two elements" (l. 15-16) renders the claim indefinite because it is not clear what two elements of the disclosed invention are being claimed. The guide element (1) of the disclosed invention is only shown in the holes of bone pieces (5). Applicant is reminded that a claim including a human being within its scope is prohibited by 35 U.S.C. § 101 (see 35 U.S.C. § 101 rejection below). There is insufficient antecedent basis for the limitation "the locking elements" (l. 20) in the claim.

In claim 23: the language "turns the spindle element or threaded rod" (l. 2) renders the claim indefinite because in claim 15 the spindle element comprises a threaded rod. Therefore, it is unclear what limitation this places on the claim. The language "the locking element" (l. 3) renders the claim indefinite because it is unclear which locking element is being claimed.

In claim 24: the language "the locking element" (l. 2) renders the claim indefinite because it is unclear which locking element is being claimed.

In claim 29: the language "two locking elements" (l. 2) renders the claim indefinite because it is misdescriptive of the disclosed invention. The two locking elements of claim 29 with the already claimed two locking elements already claimed by claim 15 or 30 would make a total of four locking elements. The disclosed invention only shows two locking elements.

In claim 30: the language "at least one locking element" (l. 3-4) and "two locking elements" (l. 13) renders the claim indefinite because it is misdescriptive of the

Art Unit: 3775

disclosed invention. This language appears to claim three locking elements. The disclosed invention only shows two locking elements. The language "means for moving the at least one locking element" renders the claim indefinite because it is unclear what is being claimed. The means in the disclosed invention include the spindle, drive unit, and motor, but claim 30 further goes on to claim the spindle, drive unit, and motor separate from the "means". Therefore, it is unclear what "means" are being claimed.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 15, 18-20, and 23-29 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 15, lines 4, applicant positively recites part of a human, i.e. "a bone segment". In claim 15, lines 15-18, applicant positively recites part of a human, i.e. "the guide element is secured in the holes of the two elements and bone segment". In claim 25, applicant positively recites part of a human (see whole claim). In claim 26, applicant positively recites part of a human (see whole claim). Thus, claims 15, 18-20, and 23-29 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. 1077 OG 24 (1987), reprinted in 1146 TMOG 24 (1993).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 15, 18, 20, 23-30 rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,986,504 to Avila (hereinafter "Avila") in view of the cited Clinical Orthopaedics article by Baumgart et al. (cited on 26 September 2007; hereinafter "Baumgart").

a. Concerning claims 15, 20, 23, and 25-30: Avila discloses a device capable of use in lengthening bones comprising guide element (50), two locking elements (10 and 11); threaded rod (6); guide slots (5); receiving opening (embodied by area that 39 enters 50); and recess (embodied by inner part of tube 51). The locking elements move in opposite directions when the threaded rod is turned (see Fig. 5). Avila does not disclose a motor and control unit.

Baumgart suggests a bone lengthening device that uses a motor drive with a gear to turn a spindle mechanism (see page 136, Materials and Methods, The Nail) and a control unit (taken to be embodied by the antenna used to control the motor) because it combines the advantages of using an internal bone device (taken to be embodied by a nail) with those of an implantable source of power (see page 136, 3rd paragraph), thus allowing manipulation of the spindle after implantation. The motor drive of Baumgart is fitted against rotation (embodied by

Art Unit: 3775

delivering torque through spindle, i.e. if it was not fitted against rotation, the motor would spin by itself). It would have been obvious to someone of ordinary skill in the art at the time of the invention to use a geared motor drive suggested by Baumgart with the invention of Avila in order to combine the advantages of using an internal bone device with those of an implantable source of power, thus allowing manipulation of the threaded rod after implantation.

b. Concerning claims 18 and 24: Avila further discloses multiple slots (5); and locking elements with round cross sections.

9. Claim 19 rejected under 35 U.S.C. 103(a) as being unpatentable over Avila in view of Baumgart as applied to claim 15 or 30 above, and further in view of US 5,626,579 to Muschler et al. (hereinafter "Muschler").

Avila, in view of Baumgart, fairly suggests the claimed invention except for the guide element comprising, at each end, radial through-openings. Muschler suggests a guide element comprising, at each end, a radial through-openings (see Figure 1A, where parts 33 go through the guide element 32) in order to allow attachment of the guide element to bone (see Figure 1A). It would have been obvious to someone of ordinary skill in the art at the time of the invention to have radial through openings at both ends of the guide element in the modified invention of Avila, in view of Baumgart and Muschler, in order to attach the guide element to the bone at both ends.

Response to Arguments

10. Applicant's arguments with respect to claims 15 and 30 have been considered but are moot in view of the new ground(s) of rejection.

11. Additionally, it is noted that applicant's description of the drawings on page 6 of the arguments filed 27 January 2009, does not appear to match the drawings filed 20 September 2005.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAY R. SIGLER whose telephone number is (571)270-3647. The examiner can normally be reached on Monday through Thursday from 8 AM to 4 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas C. Barrett can be reached on (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3775

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. R. S./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775